

PATENT

Atty. Docket No. CPC-003CPCN2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Biondi et al.

SERIAL NUMBER: Not yet assigned

ART UNIT: Not yet assigned

FILING DATE: Herewith

EXAMINER: Not yet assigned

TITLE: VENTILATOR CONTROL SYSTEM AND METHOD

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

In the Specification

On page 1, after the title "Ventilator Control System and Method", please insert the following paragraph:

--Cross-Reference to Related Applications

This is a continuation application of U.S. application number 09/660,820, filed September 13, 2000, which is a continuation of U.S. application number 09/045,461, filed March 20, 1998, now U.S. Patent No. 6,158,432, which is a continuation-in-part of U.S. application number 08/569,919, filed December 8, 1995, now U.S. Patent No. 5,931,160.--

On page 5, please delete the paragraph beginning on line 7 and ending on line 8, and substitute the following therefor:

--FIG. 11 is a flow chart of the data structure hierarchy employed by the ventilator control system.--

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In the Claims

Please cancel claims 1-10 and introduce new claims 11-38:

11. (New) A ventilator control system for controlling a ventilator pneumatic system, comprising a controller comprising a breath control structure, said controller receiving input values from a user for setting one or more breath parameters within said breath control structure and for adjusting a plurality of controls within said ventilator pneumatic system in response to the breath control structure.
12. (New) The ventilator control system of claim 11 wherein each breath parameter comprises at least one of a control setting and an alarm setting.
13. (New) The ventilator control system of claim 11 further comprising a display in communication with said controller for displaying a user interface comprising software-generated images representing status of the patient's pulmonary system and the set of breath parameters.
14. (New) The ventilator control system of claim 13 wherein the display comprises a touch-sensitive screen for receiving user input.
15. (New) The ventilator control system of claim 11 further comprising a simulator electrically coupled to the controller for simulating the status of a patient's pulmonary system in real time.
16. (New) A method for controlling a ventilator pneumatic system comprising:
receiving input values provided by a user for setting one or more breath parameters;
generating a breath control structure from said one or more breath parameters; and

adjusting a plurality of controls within said ventilator pneumatic system in response to the breath control structure.

17. (New) The method of claim 16 wherein each breath parameter comprises at least one of a control setting and an alarm setting.
18. (New) The method of claim 16 further comprising creating a breath control structure from the set of breath parameters.
19. (New) The method of claim 18 further comprising simultaneously changing the plurality of controls within the ventilator pneumatic system in response to the breath control structure.
20. (New) The method of claim 16 further comprising displaying software-generated images representing status of the patient's pulmonary system and the set of breath parameters on a display.
21. (New) A ventilator control system for simulating status of a patient connected to a ventilator pneumatic system comprising:
 - a controller comprising a breath control structure, said controller for receiving input values from a user for setting one or more breath parameters within said breath control structure;
 - a simulator electrically connected to the controller for predicting the status of a patient's pulmonary system by simulating
 - (a) an adjustment by the controller of a plurality of controls within the ventilator pneumatic system in response to said breath control structure,
 - (b) a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and

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a display in electrical communication with said simulator for providing software-generated images representing predicted status of the patient's pulmonary system and the set of breath parameters.

22. (New) The ventilator control system of claim 21 wherein each breath parameter comprises at least one of a control setting and an alarm setting.
23. (New) The ventilator control system of claim 21 wherein the user interface comprises a touch-sensitive screen.
24. (New) A method for simulating status of the pulmonary system of a patient connected to a ventilator pneumatic system comprising:
- creating a breath control structure comprising one or more breath parameters;
 - predicting the status of the patient's pulmonary system by
 - (a) simulating an adjustment to a plurality of controls within the ventilator pneumatic system in response to the breath control structure, and
 - (b) simulating a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and
 - displaying software-generated images representing the predicted status of the patient's pulmonary system and the breath control structure.
25. (New) The method of claim 24 further comprises using the controller to create at least one breath control structure from the set of breath parameters.
26. (New) The method of claim 25 further comprising simulating the adjustment of the plurality of controls within the ventilator pneumatic system in response to the breath control structure.

27. (New) A method for generating a breath control structure to control a ventilator pneumatic system comprising:

- providing a set of breath parameters, each breath parameter within the set of breath parameters including at least one of a control setting or alarm setting;
- creating a breath control structure from the set of breath parameters; and
- simultaneously adjusting a plurality of controls within a ventilator pneumatic system in response to the breath control structure.

28. (New) A method for providing a therapy to a patient connected to a ventilator pneumatic system comprising:

- providing a first breath control structure and a second breath control structure, each breath control structure comprising a plurality of breath parameters;
- adjusting a plurality of controls within said ventilator pneumatic system using the first breath control structure;
- measuring one of said plurality of breath parameters;
- adjusting said plurality of controls within said ventilator pneumatic system using the second breath control structure when one or more breath parameters exceed predetermined trigger values.

29. (New) The method of claim 28 wherein a therapy parameter comprises at least one of a time measurement and a characteristic of the patient's pulmonary system.

30. (New) A method for controlling a ventilator pneumatic system comprising:

- providing a database to a controller, said database storing patient protocols, each patient protocol comprising a set of breath control structures;
- accessing the database to select a patient protocol;
- loading a processor with the selected patient protocol; and

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using the controller to adjust a plurality of controls within the ventilator pneumatic system using the breath control structure of the selected patient protocol.

31. (New) A ventilator control system for controlling a ventilator pneumatic system comprising:
- a database for storing a plurality of patient protocols, each patient protocol comprising a set of breath control structures; and
 - a controller for adjusting a plurality of controls within the ventilator pneumatic system using the breath control structure of the selected patient protocol.
32. (New) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:
- providing a resistance parameter;
 - measuring the gas flow resistance into and out of the lungs of a patient during an inspiration phase, an exhalation phase and a post-breath phase of a breath; and
 - selectively adjusting one or more controls on the ventilator pneumatic system to compensate for the measured gas flow resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath to control respiration of said patient.
33. (New) A method of displaying historical status of the pulmonary system of a patient connected to a ventilator pneumatic system comprising:
- defining a measurement period;
 - providing a plurality of breath parameters having user defined target values and actual values, the breath parameters comprising minute volume, inspiration phase, exhalation phase, inspiration/exhalation ratio, breathing rate, spontaneous minute volume, inhale tidal volume, exhale tidal volume, and leakage;
 - measuring the actual breath parameter values during the measurement period;
 - generating an integrated graphic for displaying the target values and actual values of the plurality of breath parameters on a display; and

periodically updating the input values and measured values included in the graphic display.

34. (New) The method of claim 33 wherein the integrated graphic representing target minute volume comprises a circle having an area corresponding to the user defined target value of the minute volume.
35. (New) The method of claim 33 wherein the integrated graphic representing actual minute volume comprises a semi-transparent circle having an area corresponding to the actual value.
36. (New) The method of claim 34 wherein the integrated graphic representing target inspiration and exhalation phases comprises interspersed wedges within a target minute volume circle, wherein a target inspiration phase and a target exhalation phase form a target breath.
37. (New) The method of claim 36 wherein the integrated graphic representing measured inspiration and exhalation phases comprises interspersed semi-transparent wedges disposed over the target inspiration and exhalation phase and having an area corresponding to the actual value, wherein a measured inspiration phase and a measured exhalation phase form a measured breath.
38. (New) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:
- providing a resistance parameter;
 - setting said resistance parameter equal to a value calculated from monitored gas flow and pressure measurements for the patient, wherein said value is calculated from the following equation;
- $$\text{resistance parameter} = (\text{Inspiration Peak Pressure} - \text{End Inspiration Plateau Pressure}) / (\text{Inspiration Flow at Peak});$$

measuring the gas flow resistance into and out of the lungs of a patient during an inspiration phase, and exhalation phase, an exhalation phase and a post-breath phase of a breath; and

selectively adjusting one or more controls on the ventilator pneumatic system to compensate for the measured resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath.

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REMARKS

Amendments to the Specification

The specification has been amended to provide corrected related application information and correct an obvious typographical error.

Amendments to the Claims

Originally filed claims 1-10 are hereby cancelled, and claims 11-38 are introduced. Upon entry of this paper only claims 11-38 will be pending for this application

Applicants submit that support for claims 11-38 can be found at least on pages 32-35 of the specification as originally filed. No new matter is added.

CONCLUSION

Applicants respectfully request allowance of claims 11-38. The Examiner is invited to telephone the undersigned to address any comments or questions that the Examiner may have.

Respectfully submitted,

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MARKED-UP COPY OF AMENDMENTS TO THE SPECIFICATION

Please insert the following paragraph after the title but prior to the paragraph beginning on page one, line one.

Cross-Reference to Related Applications

This is a continuation application of U.S. application number 09/660,820, filed September 13, 2000, which is a continuation of U.S. application number 09/045,461, filed March 20, 1998, now U.S. Patent No. 6,158,432, which is a continuation-in-part of U.S. application number 08/569,919, filed December 8, 1995, now U.S. Patent No. 5,931,160.

On page 5, please delete the paragraph beginning on line 7 and ending on line 8, and substitute the following therefor:

FIG. 110 is a flow chart of the data structure hierarchy employed by the ventilator control system.

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MARKED-UP COPY OF AMENDMENTS TO THE CLAIMS

Claims 11-38 are added as follows:

11. (New) A ventilator control system for controlling a ventilator pneumatic system, comprising a controller comprising a breath control structure, said controller receiving input values from a user for setting one or more breath parameters within said breath control structure and for adjusting a plurality of controls within said ventilator pneumatic system in response to the breath control structure.
12. (New) The ventilator control system of claim 11 wherein each breath parameter comprises at least one of a control setting and an alarm setting.
13. (New) The ventilator control system of claim 11 further comprising a display in communication with said controller for displaying a user interface comprising software-generated images representing status of the patient's pulmonary system and the set of breath parameters.
14. (New) The ventilator control system of claim 13 wherein the display comprises a touch-sensitive screen for receiving user input.
15. (New) The ventilator control system of claim 11 further comprising a simulator electrically coupled to the controller for simulating the status of a patient's pulmonary system in real time.
16. (New) A method for controlling a ventilator pneumatic system comprising:
receiving input values provided by a user for setting one or more breath parameters;
generating a breath control structure from said one or more breath parameters; and

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adjusting a plurality of controls within said ventilator pneumatic system in response to the breath control structure.

17. (New) The method of claim 16 wherein each breath parameter comprises at least one of a control setting and an alarm setting.

18. (New) The method of claim 16 further comprising creating a breath control structure from the set of breath parameters.

19. (New) The method of claim 18 further comprising simultaneously changing the plurality of controls within the ventilator pneumatic system in response to the breath control structure.

20. (New) The method of claim 16 further comprising displaying software-generated images representing status of the patient's pulmonary system and the set of breath parameters on a display.

21. (New) A ventilator control system for simulating status of a patient connected to a ventilator pneumatic system comprising:

a controller comprising a breath control structure, said controller for receiving input values from a user for setting one or more breath parameters within said breath control structure;

a simulator electrically connected to the controller for predicting the status of a patient's pulmonary system by simulating

(a) an adjustment by the controller of a plurality of controls within the ventilator pneumatic system in response to said breath control structure,

(b) a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and

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a display in electrical communication with said simulator for providing software-generated images representing predicted status of the patient's pulmonary system and the set of breath parameters.

22. (New) The ventilator control system of claim 21 wherein each breath parameter comprises at least one of a control setting and an alarm setting.

23. (New) The ventilator control system of claim 21 wherein the user interface comprises a touch-sensitive screen.

24. (New) A method for simulating status of the pulmonary system of a patient connected to a ventilator pneumatic system comprising:

creating a breath control structure comprising one or more breath parameters;

predicting the status of the patient's pulmonary system by

(a) simulating an adjustment to a plurality of controls within the ventilator pneumatic system in response to the breath control structure, and

(b) simulating a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and

displaying software-generated images representing the predicted status of the patient's pulmonary system and the breath control structure.

25. (New) The method of claim 24 further comprises using the controller to create at least one breath control structure from the set of breath parameters.

26. (New) The method of claim 25 further comprising simulating the adjustment of the plurality of controls within the ventilator pneumatic system in response to the breath control structure.

27. (New) A method for generating a breath control structure to control a ventilator pneumatic system comprising:

- providing a set of breath parameters, each breath parameter within the set of breath parameters including at least one of a control setting or alarm setting;
- creating a breath control structure from the set of breath parameters; and
- simultaneously adjusting a plurality of controls within a ventilator pneumatic system in response to the breath control structure.

28. (New) A method for providing a therapy to a patient connected to a ventilator pneumatic system comprising:

- providing a first breath control structure and a second breath control structure, each breath control structure comprising a plurality of breath parameters;
- adjusting a plurality of controls within said ventilator pneumatic system using the first breath control structure;
- measuring one of said plurality of breath parameters;
- adjusting said plurality of controls within said ventilator pneumatic system using the second breath control structure when one or more breath parameters exceed predetermined trigger values.

29. (New) The method of claim 28 wherein a therapy parameter comprises at least one of a time measurement and a characteristic of the patient's pulmonary system.

30. (New) A method for controlling a ventilator pneumatic system comprising:

- providing a database to a controller, said database storing patient protocols, each patient protocol comprising a set of breath control structures;
- accessing the database to select a patient protocol;
- loading a processor with the selected patient protocol; and

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using the controller to adjust a plurality of controls within the ventilator pneumatic system using the breath control structure of the selected patient protocol.

31. (New) A ventilator control system for controlling a ventilator pneumatic system comprising:

a database for storing a plurality of patient protocols, each patient protocol comprising a set of breath control structures; and

a controller for adjusting a plurality of controls within the ventilator pneumatic system using the breath control structure of the selected patient protocol.

32. (New) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:

providing a resistance parameter;

measuring the gas flow resistance into and out of the lungs of a patient during an inspiration phase, an exhalation phase and a post-breath phase of a breath; and

selectively adjusting one or more controls on the ventilator pneumatic system to compensate for the measured gas flow resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath to control respiration of said patient.

33. (New) A method of displaying historical status of the pulmonary system of a patient

connected to a ventilator pneumatic system comprising:

defining a measurement period;

providing a plurality of breath parameters having user defined target values and actual values, the breath parameters comprising minute volume, inspiration phase, exhalation phase, inspiration/exhalation ratio, breathing rate, spontaneous minute volume, inhale tidal volume, exhale tidal volume, and leakage;

measuring the actual breath parameter values during the measurement period;

generating an integrated graphic for displaying the target values and actual values of the plurality of breath parameters on a display; and

periodically updating the input values and measured values included in the graphic display.

34. (New) The method of claim 33 wherein the integrated graphic representing target minute volume comprises a circle having an area corresponding to the user defined target value of the minute volume.
35. (New) The method of claim 33 wherein the integrated graphic representing actual minute volume comprises a semi-transparent circle having an area corresponding to the actual value.
36. (New) The method of claim 34 wherein the integrated graphic representing target inspiration and exhalation phases comprises interspersed wedges within a target minute volume circle, wherein a target inspiration phase and a target exhalation phase form a target breath.
37. (New) The method of claim 36 wherein the integrated graphic representing measured inspiration and exhalation phases comprises interspersed semi-transparent wedges disposed over the target inspiration and exhalation phase and having an area corresponding to the actual value, wherein a measured inspiration phase and a measured exhalation phase form a measured breath.
38. (New) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:
providing a resistance parameter;
setting said resistance parameter equal to a value calculated from monitored gas flow and pressure measurements for the patient, wherein said value is calculated from the following equation;
resistance parameter = (Inspiration Peak Pressure - End Inspiration Plateau Pressure)/
(Inspiration Flow at Peak);

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measuring the gas flow resistance into and out of the lungs of a patient during an inspiration phase, and exhalation phase, an exhalation phase and a post-breath phase of a breath; and

selectively adjusting one or more controls on the ventilator pneumatic system to compensate for the measured resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath.

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1. (Canceled)
2. (Canceled)
3. (Canceled)
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6. (Canceled)
7. (Canceled)
8. (Canceled)
9. (Canceled)
10. (Canceled)
11. (New) A ventilator control system for controlling a ventilator pneumatic system, comprising a controller comprising a breath control structure, said controller receiving input values from a user for setting one or more breath parameters within said breath control structure and for adjusting a plurality of controls within said ventilator pneumatic system in response to the breath control structure.

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12. (New) The ventilator control system of claim 11 wherein each breath parameter comprises at least one of a control setting and an alarm setting.
13. (New) The ventilator control system of claim 11 further comprising a display in communication with said controller for displaying a user interface comprising software-generated images representing status of the patient's pulmonary system and the set of breath parameters.
14. (New) The ventilator control system of claim 13 wherein the display comprises a touch-sensitive screen for receiving user input.
15. (New) The ventilator control system of claim 11 further comprising a simulator electrically coupled to the controller for simulating the status of a patient's pulmonary system in real time.
16. (New) A method for controlling a ventilator pneumatic system comprising:
receiving input values provided by a user for setting one or more breath parameters;
generating a breath control structure from said one or more breath parameters; and
adjusting a plurality of controls within said ventilator pneumatic system in response to the breath control structure.
17. (New) The method of claim 16 wherein each breath parameter comprises at least one of a control setting and an alarm setting.
18. (New) The method of claim 16 further comprising creating a breath control structure from the set of breath parameters.

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19. (New) The method of claim 18 further comprising simultaneously changing the plurality of controls within the ventilator pneumatic system in response to the breath control structure.
20. (New) The method of claim 16 further comprising displaying software-generated images representing status of the patient's pulmonary system and the set of breath parameters on a display.
21. (New) A ventilator control system for simulating status of a patient connected to a ventilator pneumatic system comprising:
- a controller comprising a breath control structure, said controller for receiving input values from a user for setting one or more breath parameters within said breath control structure;
 - a simulator electrically connected to the controller for predicting the status of a patient's pulmonary system by simulating
 - (a) an adjustment by the controller of a plurality of controls within the ventilator pneumatic system in response to said breath control structure,
 - (b) a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and
 - a display in electrical communication with said simulator for providing software-generated images representing predicted status of the patient's pulmonary system and the set of breath parameters.
22. (New) The ventilator control system of claim 21 wherein each breath parameter comprises at least one of a control setting and an alarm setting.
23. (New) The ventilator control system of claim 21 wherein the user interface comprises a touch-sensitive screen.

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24. (New) A method for simulating status of the pulmonary system of a patient connected to a ventilator pneumatic system comprising:
- creating a breath control structure comprising one or more breath parameters;
 - predicting the status of the patient's pulmonary system by
 - (a) simulating an adjustment to a plurality of controls within the ventilator pneumatic system in response to the breath control structure, and
 - (b) simulating a response of the patient's pulmonary system to the adjustment to the plurality of controls within the ventilator pneumatic system; and
 - displaying software-generated images representing the predicted status of the patient's pulmonary system and the breath control structure.
25. (New) The method of claim 24 further comprises using the controller to create at least one breath control structure from the set of breath parameters.
26. (New) The method of claim 25 further comprising simulating the adjustment of the plurality of controls within the ventilator pneumatic system in response to the breath control structure.
27. (New) A method for generating a breath control structure to control a ventilator pneumatic system comprising:
- providing a set of breath parameters, each breath parameter within the set of breath parameters including at least one of a control setting or alarm setting;
 - creating a breath control structure from the set of breath parameters; and
 - simultaneously adjusting a plurality of controls within a ventilator pneumatic system in response to the breath control structure.
28. (New) A method for providing a therapy to a patient connected to a ventilator pneumatic system comprising:

providing a first breath control structure and a second breath control structure, each breath control structure comprising a plurality of breath parameters;
adjusting a plurality of controls within said ventilator pneumatic system using the first breath control structure;
measuring one of said plurality of breath parameters;
adjusting said plurality of controls within said ventilator pneumatic system using the second breath control structure when one or more breath parameters exceed predetermined trigger values.

29. (New) The method of claim 28 wherein a therapy parameter comprises at least one of a time measurement and a characteristic of the patient's pulmonary system.
30. (New) A method for controlling a ventilator pneumatic system comprising:
providing a database to a controller, said database storing patient protocols, each patient protocol comprising a set of breath control structures;
accessing the database to select a patient protocol;
loading a processor with the selected patient protocol; and
using the controller to adjust a plurality of controls within the ventilator pneumatic system using the breath control structure of the selected patient protocol.
31. (New) A ventilator control system for controlling a ventilator pneumatic system comprising:
a database for storing a plurality of patient protocols, each patient protocol comprising a set of breath control structures; and
a controller for adjusting a plurality of controls within the ventilator pneumatic system using the breath control structure of the selected patient protocol.
32. (New) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:

providing a resistance parameter;
measuring the gas flow resistance into and out of the lungs of a patient during an inspiration phase, an exhalation phase and a post-breath phase of a breath; and
selectively adjusting one or more controls on the ventilator pneumatic system to compensate for the measured gas flow resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath to control respiration of said patient.

33. (New) A method of displaying historical status of the pulmonary system of a patient connected to a ventilator pneumatic system comprising:
- defining a measurement period;
 - providing a plurality of breath parameters having user defined target values and actual values, the breath parameters comprising minute volume, inspiration phase, exhalation phase, inspiration/exhalation ratio, breathing rate, spontaneous minute volume, inhale tidal volume, exhale tidal volume, and leakage;
 - measuring the actual breath parameter values during the measurement period;
 - generating an integrated graphic for displaying the target values and actual values of the plurality of breath parameters on a display; and
 - periodically updating the input values and measured values included in the graphic display.
34. (New) The method of claim 33 wherein the integrated graphic representing target minute volume comprises a circle having an area corresponding to the user defined target value of the minute volume.
35. (New) The method of claim 33 wherein the integrated graphic representing actual minute volume comprises a semi-transparent circle having an area corresponding to the actual value.

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36. (New) The method of claim 34 wherein the integrated graphic representing target inspiration and exhalation phases comprises interspersed wedges within a target minute volume circle, wherein a target inspiration phase and a target exhalation phase form a target breath.
37. (New) The method of claim 36 wherein the integrated graphic representing measured inspiration and exhalation phases comprises interspersed semi-transparent wedges disposed over the target inspiration and exhalation phase and having an area corresponding to the actual value, wherein a measured inspiration phase and a measured exhalation phase form a measured breath.
38. (New) A method of compensating for gas flow resistance into and out of the lungs of a patient connected to a ventilator pneumatic system comprising:
- providing a resistance parameter;
 - setting said resistance parameter equal to a value calculated from monitored gas flow and pressure measurements for the patient, wherein said value is calculated from the following equation;
$$\text{resistance parameter} = (\text{Inspiration Peak Pressure} - \text{End Inspiration Plateau Pressure}) / (\text{Inspiration Flow at Peak});$$
 - measuring the gas flow resistance into and out of the lungs of a patient during an inspiration phase, and exhalation phase, an exhalation phase and a post-breath phase of a breath; and
 - selectively adjusting one or more controls on the ventilator pneumatic system to compensate for the measured resistance during any one or more of the inspiration, exhalation, or a post-breath phases of the breath.

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